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Inc., a Nevada Corporation and Matthew  
5 A. Nicosia

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7 **IN THE UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA**

8 UNITED STATES OF AMERICA,  
9 Plaintiff,

10 vs.

11 VIVACEUTICALS, INC., d/b/a  
REGENECA WORLDWIDE, a  
corporation, and MATTHEW A.  
12 NICOSIA, an individual,  
13 Defendants.

Case No. 8:15-CV-1893

**ANSWER TO COMPLAINT**

Trial Date: None Set

14 **ANSWER TO COMPLAINT**

15 Defendants, VIVACEUTICALS, INC., d/b/a REGENECA WORLDWIDE, a  
16 corporation, and MATTHEW A. NICOSIA, an individual, (herein collectively  
17 “Defendants”), submit their Answer and Affirmative Defenses to the Complaint  
18 filed by Plaintiffs UNITED STATES OF AMERICA (herein collectively  
19 “Plaintiff”) on November 16, 2015 (the “Complaint”).

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**ANSWER**

1. Defendants lack sufficient information to admit or deny and therefore deny the allegations in paragraph 1 of the Complaint.
2. Defendants lack sufficient information to admit or deny and therefore deny the allegations in paragraph 2 of the Complaint.
3. Defendants deny the allegations in paragraph 3 of the Complaint.
4. Defendants deny the allegations in paragraph 4 of the Complaint.
5. Defendants deny the allegations in paragraph 5 of the Complaint.
6. Defendants admit the allegations of paragraph 6(A). Defendants deny the allegations in paragraph 6(B) of the Complaint.
7. Defendants deny the allegations in paragraph 7 of the Complaint.
8. Defendants lack sufficient information to admit or deny and therefore deny the allegations in paragraph 8 of the Complaint.
9. Defendants lack sufficient information to admit or deny and therefore deny the allegations in paragraph 9 of the Complaint.
10. Defendants lack sufficient information to admit or deny and therefore deny the allegations in paragraph 10 of the Complaint.
11. Defendants lack sufficient information to admit or deny and therefore deny the allegations in paragraph 11 of the Complaint.
12. Defendants lack sufficient information to admit or deny and therefore deny the allegations in paragraph 12 of the Complaint.

1           13. Defendants lack sufficient information to admit or deny and therefore  
2 deny the allegations in paragraph 13 of the Complaint.

3           14. Defendants lack sufficient information to admit or deny and therefore  
4 deny the allegations in paragraph 14 of the Complaint.

5           15. Defendants lack sufficient information to admit or deny and therefore  
6 deny the allegations in paragraph 15 of the Complaint.

7           16. Defendants lack sufficient information to admit or deny and therefore  
8 deny the allegations in paragraph 16 of the Complaint.

9           17. Defendants lack sufficient information to admit or deny and therefore  
10 deny the allegations in paragraph 17 of the Complaint.

11           18. Defendants lack sufficient information to admit or deny and therefore  
12 deny the allegations in paragraph 18 of the Complaint.

13           19. Defendants lack sufficient information to admit or deny and therefore  
14 deny the allegations in paragraph 19 of the Complaint.

15           20. Defendants lack sufficient information to admit or deny and therefore  
16 deny the allegations in paragraph 20 of the Complaint.

17           21. Defendants lack sufficient information to admit or deny and therefore  
18 deny the allegations in paragraph 21 of the Complaint.

19           22. Defendants lack sufficient information to admit or deny and therefore  
20 deny the allegations in paragraph 22 of the Complaint.

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1           23. Defendants lack sufficient information to admit or deny and therefore  
2 deny the allegations in paragraph 23 of the Complaint.

3           24. Defendants lack sufficient information to admit or deny and therefore  
4 deny the allegations in paragraph 24 of the Complaint.

5           25. Defendants lack sufficient information to admit or deny and therefore  
6 deny the allegations in paragraph 25 of the Complaint.

7           26. Defendants incorporate their responses to paragraphs 10-12,  
8 respectively, in response to paragraph 26 of the Complaint.

9           27. Defendants lack sufficient information to admit or deny and therefore  
10 deny the allegations in paragraph 27 of the Complaint.

11           28. Defendants lack sufficient information to admit or deny and therefore  
12 deny the allegations in paragraph 28 of the Complaint.

13           29. Defendants lack sufficient information to admit or deny and therefore  
14 deny the allegations in paragraph 29 of the Complaint.

15           30. Defendants lack sufficient information to admit or deny and therefore  
16 deny the allegations in paragraph 30 of the Complaint.

17           31. Defendants lack sufficient information to admit or deny and therefore  
18 deny the allegations in paragraph 31 of the Complaint.

19           32. Defendants lack sufficient information to admit or deny and therefore  
20 deny the allegations in paragraph 32 of the Complaint.

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1           33. Defendants lack sufficient information to admit or deny and therefore  
2 deny the allegations in paragraph 33 of the Complaint.

3           34. Defendants deny the allegations in paragraph 34 of the Complaint.

4           35. Defendants deny the allegations in paragraph 35 of the Complaint.

5           36. Defendants lack sufficient information to admit or deny and therefore  
6 deny the allegations in paragraph 36 of the Complaint.

7           37. Defendants deny the allegations in paragraph 37 of the Complaint.

8           38. Defendants deny the allegations in paragraph 38 of the Complaint.

9           39. Defendants lack sufficient information to admit or deny what actions  
10 were taken by the FDA. Defendants deny that RegeneSlim is an unapproved drug.

11           40. Defendants lack sufficient information to admit or deny and therefore  
12 deny the allegations in paragraph 40 of the Complaint.

13           41. Defendants lack sufficient information to admit or deny and therefore  
14 deny the allegations in paragraph 41 of the Complaint.

15           42. Defendants lack sufficient information to admit or deny and therefore  
16 deny the allegations in paragraph 42 of the Complaint.

17           43. Defendants lack sufficient information to admit or deny and therefore  
18 deny the allegations in paragraph 43 of the Complaint.

19           44. Defendants deny the allegations in paragraph 44 of the Complaint.

20           45. Defendants deny the allegations in paragraph 45 of the Complaint.

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1           46. Defendants lack sufficient information to admit or deny and therefore  
2 deny the allegations in paragraph 46 of the Complaint.

3           47. Defendants lack sufficient information to admit or deny and therefore  
4 deny the allegations in paragraph 47 of the Complaint.

5           48. Defendants admit that Regeneca received the referenced  
6 correspondence from the FDA. Except as otherwise admitted, Defendants deny the  
7 allegations in paragraph 48 of the Complaint.

8           49. Defendants admit that Regeneca received the referenced  
9 correspondence from the FDA. Except as otherwise admitted, Defendants deny the  
10 allegations in paragraph 49 of the Complaint.

11           50. Defendants deny the allegations in paragraph 50 of the Complaint.

12           51. Defendants admit that Regeneca received the referenced  
13 correspondence from the FDA. Except as otherwise admitted, Defendants deny the  
14 allegations in paragraph 51 of the Complaint.

15           52. Defendants deny the allegations in paragraph 52 of the Complaint.

16           53. Defendants deny the allegations in paragraph 53 of the Complaint.

17           Plaintiff's prayer for relief does not require a response, but insofar as an  
18 answer is deemed necessary, Defendants deny that Plaintiff is entitled to the  
19 requested relief or to any relief whatsoever.

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**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

**(Failure to State a Cause of Action)**

1. The Complaint, and each cause of action contained therein, fails to state facts sufficient to constitute a cause of action against Defendants.

**SECOND AFFIRMATIVE DEFENSE**

**(Performance)**

2. Defendants have fully performed any and all contractual, statutory, and other duties required of them, except for those duties as to which Defendants' performance has been excused.

**THIRD AFFIRMATIVE DEFENSE**

**(Inequity)**

3. Defendants allege that it was impossible for them to perform the obligations as alleged in the Complaint; accordingly, any recovery in this action would be unjust and inequitable.

**FOURTH AFFIRMATIVE DEFENSE**

**(Reasonableness and Good Faith)**

4. Defendants acted reasonably and in good faith at all times, based on all relevant facts and circumstances known by them at the time they so acted. Accordingly, Plaintiff is barred from any relief in this action.

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**FIFTH AFFIRMATIVE DEFENSE**

**(Laches)**

5. Defendants allege that they have suffered prejudice as a result of an unreasonable delay by the FDA. Accordingly, the FDA is barred from any relief by the doctrine of laches.

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**PRAYER**

WHEREFORE, Defendants VIVACEUTICALS, INC., d/b/a REGENECA  
WORLDWIDE, a corporation, and MATTHEW A. NICOSIA, an individual, pray  
for judgment as follows:

1. That the Complaint be dismissed, that Plaintiff take nothing pursuant to  
its Complaint and that Judgment be entered on Defendant's behalf on each of the  
counts alleged;

2. For costs of suit incurred herein, including reasonable attorney's fees;  
and

3. For such other and further relief as the Court may deem just and proper.

Dated this 8<sup>th</sup> day of April, 2016.

JULANDER, BROWN & BOLLARD

By: 

Dirk O. Julander  
Attorneys for defendants Vivaceuticals,  
Inc., d/b/a Regeneca Worldwide and  
Matthew A. Nicosia

**DEMAND FOR JURY TRIAL**

Defendants VIVACEUTICALS, Inc. and MATTHEW A. NICOSIA demand  
a jury trial in the above-captioned matter.

Dated this 8<sup>th</sup> day of April, 2016.

JULANDER, BROWN & BOLLARD

By: 

Dirk O. Julander  
Attorneys for defendants Vivaceuticals,  
Inc., d/b/a Regeneca Worldwide and  
Matthew A. Nicosia

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**PROOF OF SERVICE**

**U.S. DISTRICT COURT - CENTRAL DISTRICT OF CALIFORNIA**

At the time of service, I was over 18 years of age and **not a party to this action**. I am employed in the County of Orange, State of California. My business address is 9110 Irvine Center Drive, Irvine, CA 92618.

On April 11, 2016, I served true copies of the following document(s) described as **ANSWER TO COMPLAINT** on the interested parties in this action as follows:

**SEE ATTACHED SERVICE LIST**

**BY MAIL:** I enclosed the document(s) in a sealed envelope or package addressed to the persons at the addresses listed in the Service List and placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with Julander, Brown & Bollard's practice for collecting and processing correspondence for mailing. On the same day that the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

**BY CM/ECF NOTICE OF ELECTRONIC FILING:** I electronically filed the document(s) with the Clerk of the Court by using the CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system. Participants in the case who are not registered CM/ECF users will

1 be served by mail or by other means permitted by the court rules.

2 I declare under penalty of perjury under the laws of the United States of  
3 America that the foregoing is true and correct and that I am employed in the office  
4 of a member of the bar of this Court at whose direction the service was made.

5 Executed on April 11, 2016, at Irvine, California.

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Stephanie Hernandez

**SERVICE LIST**  
**USA vs. Vivaceuticals et. al**  
**8:15-cv-1893**

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